

Application No.: 08/821,025

Docket No.: 251502006900

**REMARKS**

Claims 68-95 are pending and were rejected in the Office action. Claims 69-73 are amended to clarify the spelling of the term "fungi," and claims 87-89 and 91-93 were amended to clarify the syntax for ranges. These amendments are non-narrowing and should clarify the spelling and syntax issues identified by the Office on page 2 of the action. Rejections concerning obviousness type double patenting and prior art are discussed hereafter.

Obviousness Type Double-Patenting Rejection

Claims 68-80, 82-86, 94 and 95 were rejected for alleged obviousness type double patenting over U.S. Patent No. 6,441,208. The applicants do not acquiesce to this rejection and file a terminal disclaimer against U.S. Patent No. 6,441,208 to render the rejection moot and expedite prosecution. A copy of the terminal disclaimer is filed herewith.

Rejections Under Barclay Alone

Claims 68-69, 76-80, 82, 84-87 and 94-95 were rejected for alleged anticipation and obviousness over Barclay (U.S. Patent No. 5,340,594). The Office states that Barclay discloses a granule composition comprising extruded microorganisms that are dead and non-disrupted, pointing to column 12, lines 32-60 of the document. While this section of the document does not describe characteristics of the extrudate, the Office concluded that the resulting extrudate inherently is granular, dead, non-disruptive and porous with diameters between 0.1 millimeters to 12 millimeters. The Office also alleges the extrudate may be porous as it is defined as an "extruded matrix" at column 12, line 47 and the cells are used for extraction (column 13, lines 13-20). The rejections respectfully are traversed.

Barclay does not anticipate or render obvious any of the claims in the present application because the extrusion product described in the document is not porous and the cells are not disrupted (*i.e.*, the cells are intact). The subject matter claimed herein also is not enabled by Barclay

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and Barclay is limited to disclosing only one type of algae. A detailed discussion of these facts follows.

First, it should be noted that not all products resulting from extrusion are porous. The porosity depends on the material being extruded and the conditions of extrusion, including, for example, the temperature and pressure. Simply because a document refers to extrusion, even of cells, there is no reason to believe that the resulting extruded product will be porous. Indeed, the reason why Barclay extrudes cells is to produce a food product. For example, Barclay is in the field of foods and feedstuffs, and it is known that spaghetti is an extruded product. Spaghetti is not porous. Therefore, whether an extruded product is porous or not depends upon the material being extruded, and the extrusion conditions.

The Office states that Barclay inherently teaches porous particles because it refers to an "extruded matrix" (column 12, line 47). As noted above, this phrase alone does not indicate that the matrix is porous. In fact, there is nothing porous about an extruded matrix, since an extruded matrix could easily and equally be applicable to a non-porous material, such as spaghetti. With respect, it is not understood why the Office believes this terminology suggests porosity, when the phrase means nothing more than a material that has been extruded? Certainly, this phrase would not be understood by a person skilled in the art as indicating porosity, in any way, shape or form. With respect, the Office is stretching the meaning of this phrase, and no technical evidence is offered for asserting that a person skilled in the art would understand this terminology to indicate porosity.

There is no disclosure in Barclay of extracting cell components such as polyunsaturated fatty acids (PUFAs) from the extruded product. Barclay refers to extracting omega 3 highly unsaturated fatty acids (HUFAs) but the extraction process has nothing to do with extrusion. The reference to extraction concerns lysing the cells of the microorganisms to liberate these fatty acids (see the sentence spanning columns 4 and 5). Thus, Barclay teaches that in order to increase the bioavailability of these fatty acids, one could first disrupt the cells. There is no extraction of the fatty acids from intact cells. There also is no extraction of fatty acids after extrusion. Thus, there is no evidence that Barclay discloses that are porous and there is no reason to make the extruded product of Barclay porous.

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Furthermore, it would not be obvious to try and make the extruded products of Barclay porous. Given that extruded products such as spaghetti are not porous, and this is a foodstuff which is in the same field as Barclay, the evidence suggests Barclay produced non-porous particles.

Second, Barclay repeatedly refers to disruption of cells to liberate fatty acids, and therefore, this document does not teach intact or non-disrupted cells. As mentioned earlier, Barclay teaches that one can increase the bioavailability of the fatty acids by lysing the cells (the sentence spanning pages 4 and 5). This teaching is directly opposite to the present application, where the cells remain intact and non-disrupted, and components are extracted from whole cells inside the granules (e.g., fatty acids). Barclay teaches the opposite, that one should break open the cells to obtain the fatty acids.

The production and use of disrupted cells, not intact cells, are disclosed in several other sections of Barclay. For example, column 5, at lines 54 and 55 refers to "rupturing the micro organism cells." Column 13, at lines 43 to 45, refers to the cells that "can be ruptured or permeabilized." Teachings of Barclay therefore are directly contrary to the present application. Barclay suggests that if one wants to extract polyunsaturated fatty acids, then one needs to disrupt the cells. In the present application, the inventors have done precisely the opposite. The cells non-disrupted, and intact, and fatty acids are extracted from intact cells inside the granules.

Third, in contrast to the disclosure of the present application, Barclay teaches little about the composition to be extruded, and provides no teaching of the extrusion and drying conditions required for yielding granules having the characteristics specified in claim 68. Thus Barclay does not enable the subject matter claimed herein. For example, the Office has referred to the sentence concerning extrusion temperatures and pressures, at column 12, lines 40 to 43 of Barclay. This sentence adds little more than what would be known to the person skilled in the art, and which has been argued above. That is to say, extrusion can produce a wide variety of products, depending on the conditions. As producing porous and non-porous extruded products depends upon conditions such as temperature and pressure, this sentence tells the person skilled in the art nothing more that porous or non-porous products are theoretically available depending on the extrusion conditions. It does not teach how porous granules can be made. It does not outline the conditions for producing porous granules. It does not discuss important parameters such as pressure, moisture content, or

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other conditions that might enable one to produce a porous product. In other words, Barclay does not enable porous granules, because it does not explicitly teach the extrusion conditions that would allow one to make a porous (rather than a non-porous) extrudate. For these reasons, Barclay does not enable a person skilled in the art to arrive at the products of claim 68.

Fourth, it also should be noted that Barclay does not disclose, teach or suggest the subject matter of dependent claims 69-75, which cover fungi, yeast and bacteria. Barclay clearly limits its teachings and disclosure to strains of unicellular microorganisms that are members of the order *Thraustochytriales*. At column 15, line 25 to column 16, line 31, Barclay explains that while there was some uncertainty as to whether microorganisms of the order *Thraustochytriales* are fungi or algae, it is concluded that *Thraustochytriales* are completely separate from fungi, are in a completely different kingdom from fungi, and are most closely related to red and brown algae according to genetic studies and taxonomic systems (column 16, lines 3-10 and lines 14-26). Thus, Barclay should be interpreted as being limited to specific algae organisms and does not disclose, teach or suggest granules composed of fungi, yeast or bacterial microorganisms.

Accordingly, Barclay does not anticipate or render obvious the claimed subject matter because it fails to disclose, teach or suggest porous and intact granules, and fails to enable the production of such granules. The document also should be interpreted as being limited to a particular class of algae and not the fungi, yeast or bacteria claimed herein.

Rejection of Claims for Alleged Obviousness in View of the Combination of Barclay With Other Documents

Claims 68-95 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barclay in combination with Carduck, Akimoto, Casey and Remington. The rejection respectfully is traversed on several grounds.

The person skilled in the art would not combine Barclay with any of the other four documents that the Office cited. Akimoto concerns extraction of arachidonic acid with solvent. Casey concerns extraction of TAPS from *Pichia* using a solvent. Both of these documents concern the extraction of a compound from cells. That is completely different from the sphere of Barclay.

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Barclay refers to feedstuff for animals. It does not extract any compounds from the cell. It is not concerned with the isolation of a desired compound from a biomass.

The closest Barclay gets to extraction is to suggest that opening the cells first is required to increase the bioavailability of fatty acids to the animal who is given the feed. However, Barclay does not teach the extraction of PUFAs. It is not concerned with the isolation of any fatty acids. It simply suggests lysing the cells before they are incorporated into an animal feed. A person skilled in the art would not combine a document concerning animal feed with a document concerning extraction of valuable compounds from the cells. Barclay is of no assistance whatsoever to a person skilled in the art in increasing the yield of an isolated compound from microbial cells. Therefore, the combination of Barclay with any of the other documents, in particular Akimoto or Casey, is not one the person skilled in the art would make.

In any event, the teaching of Barclay is restricted to the specific types of algae referenced therein. There is no suggestion that Barclay contemplated cells other than algal microorganisms. This therefore is further evidence that Barclay is in a different field from Akimoto, which refers to fungi, and Casey, which refers to yeast. There is no reason why a person skilled in the art would combine Barclay, which is restricted to certain types of algae, with documents concerning yeast and fungi. Therefore, the claims of the present Application are not obvious over the prior art cited by the Examiner.

The arguments for combining Barclay with Carduck are not understood. As has been mentioned before, Carduck concerns active yeast compositions that can be re-hydrated. The yeast in Carduck are alive, and not dead. In the present application, the cells are not alive. They are dead. This is totally opposite to Carduck. The Office therefore cannot arrive at the subject matter of the present claims by combining Barclay and Carduck. Indeed, they are in totally different fields, and Carduck teaches that the cells should be live, which is contrary to the present application. Thus, Carduck teaches away from the claimed subject matter. It is therefore impossible to combine Carduck and Barclay and arrive at the subject matter of the present invention. Quite simply, the person skilled in the art would not make this combination.

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The Office also referred to the document by Remington. This document however refers to tableting. It makes no mention of extruding cells, and the document does not address the difficulties encountered with the complex mixture of cells such as a biomass. Remington is cited by the Office to state that particle size or distribution can be controlled by various conditions. This does not teach a person skilled in the art any more than he/she knew already, and it does not seem to advance the Examiner's case. Where does Remington teach that the extrudate should be porous? Where does Remington teach that the cells should be dead? Remington does not teach that the cells should be non-disrupted, and therefore intact, nor does it describe the extrusion conditions that would enable this to happen (rather than the cells being disrupted due to a too high temperature or pressure). Quite simply, the Remington citation is too distant and lacking in relevance, to render the current claims obvious, in combination with any other document the Office cited. There was therefore no reason or expectation of success of being able to arrive at the granules now claimed from Remington.

Further, the claims cannot be obvious if the Office requires five documents, in different fields, to reject the claimed subject matter. The Office appears to be using impermissible hindsight, and accordingly, the combination of documents is improperly assembled. Indeed, combining five documents from five different fields suggests that the claimed subject matter is not straightforward or routine and therefore not obvious.

Accordingly, the subject matter of claims 68-95 are not rendered obvious by the combination of documents cited with Barclay as there was no motivation to combine the documents with one another and because the documents are combined only by using impermissible hindsight. Thus, it is respectfully requested that the Office withdraw the rejection of claims 68-95 in view of the facts set forth above.

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**CONCLUSION**

The applicants do not acquiesce to the obvious type double patenting rejection proposed by the Office and file a terminal disclaimer herewith to render the rejection moot. Claims 68-69, 76-80, 82, 84-87 and 94-95 are novel and not obvious in view of Barclay alone because the document fails to disclose, teach or suggest porous and non-disrupted granules, fails to enable the production of granules having the claimed characteristics, and should be interpreted as being limited to extrudates of a specific class of algae. Claims 68-95 are not obvious in view of Barclay in combination with other cited documents as there was no motivation to combine the documents with one another and because the documents are combined only by using impermissible hindsight. Accordingly, it is respectfully requested that the Office withdraw rejections pertaining to the claimed subject matter and issue a notice of allowance.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 251502006900. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By   
Bruce D. Grant  
Registration No.: 47,608  
MORRISON & FOERSTER LLP  
3811 Valley Centre Drive, Suite 500  
San Diego, California 92130  
(858) 720-7962